
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

BUZZIE SMITH, individually and on behalf
of the Heirs and Estate of Charles A. Smith,
Deceased,

Plaintiff,

v.

TERUMO CARDIOVASCULAR SYSTEMS
CORPORATION; IHC HEALTH
SERVICES, INC.; INTERMOUNTAIN
MEDICAL CENTER; INTERMOUNTAIN
HEALTH CARE, INC.,

Defendants.

**SEALED MEMORANDUM DECISION
AND ORDER GRANTING
TERUMO CARDIOVASCULAR'S
[153] MOTION TO EXCLUDE
SHANE FROEBE**

Case No. 2:12-cv-00998-DN

District Judge David Nuffer

The decedent Charles A. Smith (“Mr. Smith”), represented in this litigation by Buzzie Smith (“Mrs. Smith”), underwent surgery on his heart in September 2010. There were problem during the surgery. Eleven months later, Mr. Smith passed away. Mrs. Smith brings this action against the hospital and a manufacturer of a device used during the surgery.¹ To defend against Mrs. Smith’s claim of negligence, the hospital offers Shane Froebe’s (“Mr. Froebe”) expert opinion and testimony. Defendant Terumo (“Terumo”) moves (“Motion”) to exclude Mr. Froebe’s opinion and testimony.² Defendants IHC Health Services, Inc., Intermountain Medical

¹ Amended Complaint, [docket no. 17](#), filed October 7, 2013.

² Terumo Cardiovascular Systems Corporation’s Motion to Exclude Shane Froebe (“Motion”), [docket no. 153](#), filed May 12, 2017.

Center, and Intermountain Health Care, Inc. (“Intermountain”) opposes the Motion (“Opposition”).³ Terumo replies in support of the Motion.⁴

As set forth below, Mr. Froebe is not qualified to offer an opinion on an alleged defect in the device used during the surgery and the methodology he uses to formulate that opinion is not reliable. The Motion is GRANTED.

Contents

| | |
|--|----|
| Background | 2 |
| Discussion | 3 |
| 1. Mr. Froebe lacks the necessary qualifications to opine on an alleged defect in the System 1 | 6 |
| 2. Even if Mr. Froebe is qualified to opine on a defect in the System 1, his opinion is not reliable | 8 |
| Order | 11 |

BACKGROUND⁵

On September 13, 2010, Mr. Smith underwent heart valve replacement surgery (“September 2010 surgery”).⁶ As part of the surgery, a Terumo Advanced Perfusion System 1 heart/lung bypass machine (“System 1”) was used.⁷ The System 1 was to provide for the circulation of blood and oxygen through Mr. Smith’s body while surgery was being performed on his heart valve.⁸ At some point, the System 1 stopped working for 10–11 minutes.⁹ Eleven

³ Intermountain Medical Center’s Memorandum in Opposition to Terumo Cardiovascular System Corporation’s Motion to Exclude Shane Froebe (“Opposition”), [docket no. 183](#), filed under seal June 13, 2017.

⁴ Terumo Cardiovascular Systems Corporation’s Reply in Support of its Motion to Exclude Shane Froebe (“Reply”), [docket no. 197](#), filed June 20, 2017.

⁵ As specified in the other decisions regarding motions to limit and exclude in this case, the undisputed material facts will be determined in the rulings on the motions for summary judgment. The facts described below are provided only for context and are taken as alleged in the Complaint.

⁶ Complaint ¶ 11.

⁷ *Id.* ¶ 12.

⁸ *Id.* ¶ 13.

⁹ *Id.* ¶¶ 15–17; although the Complaint fails to specify how many minutes the bypass machine was not working, the parties seem to agree on between 10 and 11 minutes. *See* Motion at 4.

months later, on August 6, 2011, Mr. Smith passed away from a myocardial infarction, (*i.e.*, heart attack).¹⁰

Intermountain hired Shane Froebe, a licensed perfusionist, to offer opinions regarding the standard of care applicable to the perfusion care provided to Mr. Smith during the September 2010 surgery and to offer his conclusion that the failure of the System 1 did not result from operator error of hospital staff.¹¹ Mr. Froebe's ultimate conclusion is as follows:

I would say that with the information I've been provided that the likelihood of the cause of the situation was from a system malfunction or some type of software malfunction that did not allow forward flow to occur. . . . And not having forward flow, even though the RPMs are increasing and decreasing, that would lead me to believe there was something other than air, decoupling, afterload resistance based off of backflow alarms. So with the information that I've received and the recall notices that we have received, it would tend to lead me to believe that it was a software issue. Again, when I say "software," a computer software issue.¹²

DISCUSSION

Terumo does not dispute that Mr. Froebe "[m]ay know the functions or inputs necessary to successfully perform perfusion,"¹³ and Terumo "does not challenge the admissibility of Mr. Froebe's standard of care opinions."¹⁴ However, Terumo argues that the portions of Mr. Froebe's opinions and testimony regarding the presence of an alleged defect in the System 1 should be excluded for two reasons. First, Terumo argues that Mr. Froebe is not qualified to "testify about a potential defect in the System 1 that may (or may not) have exhibited itself during the [September 2010 surgery]" because he "has no experience in product design,

¹⁰ *Id.*

¹¹ IHC Health Services' Rule 26(a)(2) Expert Disclosures at 1–2, [docket no. 144](#), filed March 16, 2017.

¹² Opposition, Exhibit L, Excerpts of Expert Deposition of Shane Froebe ("Froebe Deposition") at 100:4–8, 101:2–12, [docket no. 183-12](#), filed June 13, 2017.

¹³ Motion at 6.

¹⁴ *Id.* at 4.

development, or manufacture.”¹⁵ And second, Terumo argues that because “Mr. Froebe has engaged in nothing more than a review of Terumo safety notices and deposition testimony to conclude it is possible the System 1 malfunctioned[,]”¹⁶ Mr. Froebe has not “engage[d] in any analysis, let alone a reliable analysis to conclude that it was possible that the System 1 malfunctioned.”¹⁷

Federal Rule of Evidence 702 establishes the standard for the admissibility of expert testimony.

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.¹⁸

“Under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.”¹⁹ The inquiry of scientific reliability is flexible and focuses on principles and methodology.²⁰ The Supreme Court has offered several nonexhaustive factors that a court may rely on for determining reliability such as, whether the testimony can be tested, has been peer reviewed, has a known or potential rate of error, and has attracted acceptance in the relevant scientific community.²¹

¹⁵ *Id.* at 2.

¹⁶ *Id.* at 9.

¹⁷ *Id.* at 10.

¹⁸ Fed. R. Evid. 702.

¹⁹ *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993).

²⁰ *See Id.* at 595.

²¹ *See Id.*

District courts serve as the gatekeepers of expert evidence, and must therefore decide which experts may testify and present evidence before the jury.²² Courts are given “broad latitude” in deciding “how to determine reliability” and in making the “ultimate reliability determination.”²³ The Federal Rules of Evidence, however, generally favor the admissibility of expert testimony.²⁴ Excluding expert testimony is the exception rather than the rule, and often times the appropriate means of attacking shaky but admissible evidence is through vigorous cross-examination, and the presentation of contrary evidence.²⁵ “[T]he Federal Rules of Evidence favor the admissibility of expert testimony, and [courts’] role as gatekeeper is not intended to serve as a replacement for the adversary system.”²⁶

The inquiry into whether an expert’s testimony is reliable is not whether the expert has a general expertise in the relevant field, but whether the expert has sufficient specialized knowledge to assist jurors in deciding the particular issues before the court.²⁷

Expert testimony is subject to Federal Rule of Evidence 403. “The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.”²⁸

In determining whether expert testimony is admissible the first step is to determine whether the expert is qualified, and then if the expert is qualified determine whether the expert’s

²² *See Id.*

²³ *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 142 (1999), (citing *General Electric Co. v. Joiner*, 522 U.S. 135 (1997)).

²⁴ *See Daubert*, 509 U.S. at 588.

²⁵ *See Fed. R. Evid. 702* Advisory Notes.

²⁶ *THOIP v. Walt Disney Co.*, 690 F. Supp. 2d 218, 230 (S.D.N.Y. 2010).

²⁷ *Kumho*, 526 U.S. at 156.

²⁸ *Fed. R. Evid. 403.*

opinion is reliable by assessing the underlying reasoning and methodology.²⁹ If the expert is qualified and the opinion reliable, the subject of the opinion must be relevant; i.e. the opinion must “help the trier of fact to understand the evidence or to determine a fact in issue.”³⁰ “Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.”³¹

**1. Mr. Froebe lacks the necessary qualifications to opine
on an alleged defect in the System 1**

In Mr. Froebe’s opinion, “the failure of flow was the result of some type of software flaw or failure, possibly together with a faulty air bubble detector system”³² in the System 1. Despite acknowledging that Mr. Froebe is an expert in perfusion and possesses the requisite knowledge to *operate* the System I, Terumo argues that “expertise in proper perfusion techniques is not sufficient to analyze the design and technical functionality of a heart bypass machine.”³³ Absent the appropriate qualifications based on necessary engineering or mechanical knowledge, Terumo maintains that Mr. Froebe cannot “say, with any degree of expertise and reliability, that the System 1 malfunctioned or was defective.”³⁴

To qualify as an expert under Federal Rule of Evidence 702, the expert must have “such skill, experience or knowledge in that particular field as to make it appear that his opinion would rest on substantial foundation and would tend to aid the trier of fact in his search for truth.”³⁵

“[A]s long as an expert stays within the reasonable confines of his subject area . . . a lack of

²⁹ *U.S. v. Nacchio*, 555 F.3d 1234, 1241 (10th Cir. 2009).

³⁰ *Fed. R. Evid. 702* (emphasis added).

³¹ *Daubert*, 509 U.S. at 591.

³² Froebe Deposition at 98:15–18.

³³ Motion at 9.

³⁴ *Id.*

³⁵ *LifeWise Master Funding v. Telebank*, 374 F.3d 917 (10th Cir. 2004) (internal quotation marks and citation omitted).

specialization does not affect the admissibility of [the expert] opinion, but only its weight.”³⁶

“The dispositive question” is whether the opinion that the expert offers can be considered

“within the reasonable confines of [the expert’s] subject area.”³⁷

Mr. Froebe’s own admissions show that his ultimate opinion that the System 1 contained a defect is outside the reasonable confines of his expertise as a perfusionist. Immediately after reiterating his ultimate conclusion that “there was some type of issue . . . that causes forward flow issues”³⁸ in the System 1, Mr. Froebe admits that he is not an engineer and does not intend to offer any sort of engineering opinion:

I am not an engineer. And so I do not know what necessarily caused the fault of forward flow with [the perfusionist who performed the perfusion during the September 2010 surgery], other than the opinions that I formulated based off of the depositions and stuff that I’ve read.³⁹

The issuance of a field safety notice by Terumo is key to Mr. Froebe’s opinion that the System 1 suffered from a computer software issue:

So with the information that I’ve received and the recall notices that we have received, it would tend to lead me to believe that it was a software issue. Again, when I say “software,” a computer software issue.⁴⁰

However, when Mr. Froebe is asked about his understanding of the content of the Terumo field safety notice, he admits that he does not have the specialized electrical engineering or computer programming expertise that would allow him to offer an opinion on *why* the issues described in the notice might occur:

Q: But you wouldn’t purport to know exactly how that happened in this case, if it did?

³⁶ *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001) (internal citation omitted).

³⁷ *Id.*

³⁸ Froebe Deposition at 99:9–12.

³⁹ *Id.* at 99:13–100:20.

⁴⁰ *Id.* at 101:8–12.

A: I'm not an electrical engineer or computer programmer, so I could not go into the detail about how that would happen.⁴¹

This admitted lack of electrical engineering or computer programming expertise erodes the foundation of Mr. Froebe's opinion regarding an alleged defect in the System 1. If Mr. Froebe cannot understand or provide an explanation for the issue that leads him to the conclusion that the System 1 contained a defect, he cannot provide testimony that aids the jury in their role as fact finders. It is therefore appropriate to exclude him from testifying on this issue.

2. Even if Mr. Froebe is qualified to opine on a defect in the System 1, his opinion is not reliable.

Terumo contends that even if Mr. Froebe is qualified to opine on a potential defect in the System 1, the process by which he arrived at that opinion is unreliable.⁴² To form his opinions, Mr. Froebe reviewed depositions, reports, and systems logs.⁴³ Terumo argues that Mr. Froebe's reliance on the depositions of others and the failure to conduct any sort of testing cannot be considered to be a reliable analysis supporting the conclusion that the System 1 suffers from a defect.⁴⁴

"To assist in the assessment of reliability," a district court may consider "four nonexclusive factors."⁴⁵ These include:

(1) whether the opinion at issue is susceptible to testing and has been subjected to such testing; (2) whether the opinion has been subjected to peer review; (3) whether there is a known or potential rate of error associated with the methodology used and whether there are standards controlling the technique's

⁴¹ *Id.* at 101:17–21.

⁴² Motion at 9.

⁴³ Froebe Deposition at 6:12–13:25.

⁴⁴ Reply at 4–5.

⁴⁵ *Goebel v. Denver & Rio Grande W. R. Co.*, 346 F.3d 987, 991 (10th Cir. 2003).

operation; and (4) whether the theory has been accepted in the scientific community.⁴⁶

“[A] district court may properly exclude [expert] testimony” when the opinion evidence “is connected to existing data only by the *ipse dixit* of the expert” such that “there is simply too great an analytical gap between the data and the opinion offered.”⁴⁷ “Under *Daubert*, ‘any step that renders the analysis unreliable . . . renders the expert’s testimony inadmissible.’”⁴⁸ “It is critical that the district court determine ‘whether the evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist.’”⁴⁹

This analytical gap exists when an expert report fails to include the expert’s attempts to test his theory, as a “key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested.”⁵⁰ The Tenth Circuit has held that, although testing is not always required to satisfy the reliability threshold of Rule 702, it is particularly important where the basis for the expert opinion is subject to debate.⁵¹

Although Mr. Froebe’s proposed testimony fails under each of the four *Daubert* factors,⁵² his failure to test his theory of renders his opinion unreliable at the outset. Without testing of any kind, Mr. Froebe’s opinion has an analytical gap. He states that he formulated his opinions based

⁴⁶ *Id.* at 991–992 (quoting *Daubert*, 590 U.S. at 593–94).

⁴⁷ *Heer v. Costco Wholesale Corp.*, 589 Fed. App’x 854, 861 (10th Cir. 2014) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)) See *Heer* 589 Fed. App’x at 861 at n. 4 (“‘Ipse dixit’ is Latin for ‘He, himself, said it,’ and is used to identify an unsupported statement that rests solely on the authority of the person who makes it.” (citing *Black’s Law Dictionary* 905 (9th ed.2009))).

⁴⁸ *Gobel* at 346 F.3d at 992 (quoting *Mitchell v. Genecorp Inc.*, 165 F.3d 778, 782 (10th Cir. 1999)).

⁴⁹ *Id.* (quoting *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996)).

⁵⁰ *Daubert*, 509 U.S. at 593

⁵¹ *Heer*, 589 F. App’x at 862 (citing *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1235–36 (10th Cir. 2004)).

⁵² Indeed, nothing in Mr. Froebe’s deposition testimony indicates that his opinion has been subjected to peer review, that there is a known potential rate of error with, or standards controlling, his methodology, or a general acceptance of his opinion in the scientific community.

on a review of the depositions, reports, and system logs.⁵³ However, nothing in his deposition testimony indicates that, after consulting those materials and developing a theory that the System 1 might have a defect, he made any attempt to test that theory on other System 1 machines. Instead, after taking the field safety notice issued by Terumo into account, Mr. Froebe offers that “the failure of the flow was the result of some type of software flaw or failure, possibly together with a faulty air bubble detector system.”⁵⁴ The analytical leap to this conclusion is debatable, making testing essential for support of Mr. Froebe’s conclusion. His opinion, lacking testing, must therefore be considered unscientific speculation.

Because Mr. Froebe relies exclusively on the accounts and reports of others, rather than a rigorous scientific and analytical process of his own to arrive at a reliable opinion, it is unsurprising that his deposition would include the admission that he cannot explain why the System 1 used in the September 2010 surgery performed in the manner that it did. When asked if he could explain how the alleged software issue could have caused the forward flow issue in the System 1, Mr. Froebe is unable to offer further explanation:

Q: But you wouldn’t purport to know exactly how that happened in this case, if it did?

A: I’m not an electrical engineer or computer programmer, so I could not go into the detail about how that would happen.⁵⁵

Mr. Froebe cannot offer an expert opinion regarding an alleged product defect, when he has not attempted to test his theory and cannot adequately explain the alleged defect, and, in particular, how the type of machine in question behaved as a result of that defect. The analytical

⁵³ Froebe Deposition at 6:12–13:25.

⁵⁴ *Id.* at 98:15–18.

⁵⁵ *Id.* at 101:17–21.

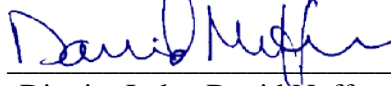
gap between the data and his opinion, without the support of testing, is too great for Mr. Froebe's opinion to be considered reliable under Rule 702. Exclusion is appropriate.

ORDER

IT IS HEREBY ORDERED that Terumo Cardiovascular Systems Corporation's Motion to Exclude Shane Froebe⁵⁶ is GRANTED.

Signed August 7, 2017.

BY THE COURT



District Judge David Nuffer

⁵⁶ Terumo Cardiovascular Systems Corporation's Motion to Exclude Shane Froebe, [docket no. 153](#), filed May 12, 2017.

United States District Court
for the
District of Utah
August 7, 2017

*****MAILING CERTIFICATE OF THE CLERK*****

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